Life Science Companies React to Recent Changes in Meeting-Related PhRMA Code Guidance

Revisions focus on alcohol, repeat attendance

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In early 2022, IQVIA surveyed life science manufacturers to assess the impact of the recent changes to the Pharmaceutical Research and Manufacturers of America Code on Interactions with Health Care Professionals (PhRMA Code) on their interactions with healthcare providers (HCPs). The changes mostly impact the conduct of speaker programs and are effective as of January 1, 2022.

- The purpose of a speaker program should be to present substantive educational information designed to help address a bona fide educational need among attendees, considering recent substantive changes in relevant information (e.g., new medical or scientific information or a new FDA-approved indication for the product) or the importance of the availability of such educational programming[1]
- Pharmaceutical companies should not pay for or provide alcohol in connection with speaker programs [and] high-end restaurants and other such venues are not appropriate locations for speaker programs[1]
- Repeat attendance at a speaker program on the same or substantially the same topic where a meal is provided to the attendee is generally not appropriate unless the attendee has a bona fide educational need to receive the information presented[1]
- Attendance by speakers as participants at programs after speaking on the same or substantially the same topic is generally not appropriate [and] attendance by friends, significant others, family members and other guests of a speaker or invited attendee is not appropriate, unless these individuals have an independent, bona fide educational need to receive the information presented[1]

SURVEY RESULTS

Alcohol at speaker programs

Respondents were surveyed across companies of varying sizes and types, with the experiences of large enterprises being the most prominent. Survey results revealed an interesting split in how companies will institute changes around alcohol:

- The first group will not offer alcohol. This is either in line with the revised PhRMA Code or because their policies never allowed it
- The second group shows a strong preference to having alcohol at events; however, this will simply be an accommodation at the attendees' expense

The preference for allowing alcohol at speaker programs is very strong and for companies that will have alcohol available in some degree, it will be available across all event types (e.g., advisory boards, consulting meetings, out of office meals).

ATTENDANCE AT SPEAKER PROGRAMS

A majority (78%) of respondents permit repeat attendance at speaker programs, with 26% indicating that it is allowable only after a certain period of time has passed.

Attendance, with or without the passage of time, is dependent on demonstrating that there is a justifiable need for the HCP to receive the information. Having or implementing a process to document an appropriate business needs justification (needs assessment) for these events and programs is an important part of showing the value of the program, but also demonstrates the importance and necessity of these activities. This should be a required part of a manufacturer's end-to-end HCP engagement management process, whether the process is system-driven or manual. A important part of the needs assessment process is identifying the speaker (and the criteria used to select this individual) as well as determining the appropriate audience who should receive the information.

CONTENT MANAGEMENT AND USE

Manufacturers continue to sponsor speaker programs for which the content has not changed for up to two years after the first program was held.

However, a little over 25% will reuse content if they meet attendance needs.

It should be noted that "content reuse" can mean many things such as making no edits at all, as well as using key parts of the information or messaging in new materials. Continuation of programs and events should be documented in the needs assessment process described above, and reuse of content and materials should be periodically evaluated through a company's Medical-Legal-Regulatory (MLR) review process to confirm appropriate use and audience in addition to identifying any necessary updates.

VENUE SELECTION

The revised PhRMA Code states, "Luxury resorts, high-end restaurants, and entertainment, sporting, or other recreational venues or events are not appropriate."[2] Nearly all respondents are making some degree of changes to venues, with a large majority likely instituting changes for reasons outside of the PhRMA Code (e.g., COVID-19).

Changes that were already happening due to other circumstances such as a shift to more virtual events than live programs, were accelerated by the guidance in the revised PhRMA Code. Venue selection for virtual events changed to selecting a technology provider instead of finding a traditional venue for an in-person meeting, which would also impact provision of meals and alcohol.

As part of the needs assessment process, companies should review the planned program delivery method, which includes venue selection. Should the program be virtual, or will the message be better delivered and received at an in-person setting?

APPLICATION TO OTHER AUDIENCES

The focus of the PhRMA Code is a company's interactions with HCPs.

For companies that sponsor patient-focused events, 65% indicated that they will apply the same policy for alcohol provision to those activities.

Considerations for applying the same policy across multiple event types include ease of planning and scheduling events, simplified monitoring and auditing processes, and controlling costs.

WHAT'S NEXT?

We recommend reviewing your existing compliance policies and procedures, compliance training content, and auditing & monitoring programs to identify changes necessary to align with new PhRMA Code guidance.

- Review and update policy definitions and process steps for conducting engagements
- Revise compliance training content and materials to provide updated information in line with PhRMA guidance and company policies and SOPs
- Make sure auditing & monitoring processes and materials enable the assessment of new and updated guidance and changes in your own policies

HOW CAN IQVIA'S COMPLIANCE CONSULTING TEAM HELP?

We understand how busy you are. And we know how much time it takes to review everything, update documents, gain consensus among all the reviewers, and then train everyone on the updated guidance.

We can take that burden off your plate. We will conduct a thorough review of your compliance materials, identify necessary updates, and then work with you to implement the changes, including facilitating the internal review process, communicating with the appropriate stakeholders, and conducting informational sessions for specific audiences. We can even help after implementation by auditing & monitoring certain activities to make sure guidance provided in your policies and training programs are followed.

For additional information or to speak with a representative from our consulting team, please visit Commercial Compliance - IQVIA.

About the Author: Regina leads the US Commercial Compliance Consulting team at IQVIA and has 20+ years of combined life sciences industry and consulting experience for compliance-driven initiatives and programs, especially those focused on process design and optimization. She has strong domain expertise in medical affairs, grants & IIT/IIS management, materials review processes, and transparency reporting. Regina is a certified Project Management Professional (PMP) and received an MBA with a specialization in project management from Jones International University. She also holds a Graduate Certificate in pharmaceutical and medical device law and compliance from Seton Hall University School of Law.

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